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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,472	12/29/2000	Dinesh Mody	FMT1P028	7176
758	7590	03/28/2006	EXAMINER	
FENWICK & WEST LLP SILICON VALLEY CENTER 801 CALIFORNIA STREET MOUNTAIN VIEW, CA 94041			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,472

Applicant(s)

MODY

Examiner

david shay

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 28, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-22,25-33,40-54,58-91,96,97,100-107,225,229-255,282 and 284-300 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>July 28, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,5-22,25-33,40-54,58-91,96,97,100-107,225,229-255,282 and 284-300.

Applicant argues that Roth et al teaches against ablating. The examiner notes that passage discussed by applicant, but does not consider this to prevent the anticipation of applicant's claimed invention. Firstly, it is noted that the teachings of Roth et al allow for minimized ablation within its four corners (see, for example column 7, lines 49-53 and column 8, lines 47-55). Secondly, the meaning of the term "ablation" as used by Roth et al (tissue vaporization) and the meaning of the term "ablation" as it is used in the instant disclosure are substantially different. Roth et al equate ablation to tissue vaporization (see, for example column 7, lines 49-53 and column 8, lines 47-55) as distinct from lesion forming, necrosis, or even burning ton the point of carbonization. Applicant's original disclosure, however, uses the term ablation as synonymous with lesion forming (see paragraph [0057] for example). Thus it is clear that the meaning of the term "ablation" as used in the claims refers to a process covered by the intended lesion forming of Roth et al.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 9, 43-45, 106, 298 and 299 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roth et al.

See Figures 1-7 and columns 8, line 6 to column 17, line 15.

Claims 1, 9, 43-45, 96, 97, 298, and 299 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al ('807) in combination with Costello et al. Lennox et al, ('807) teach the use of flexible sheath with a window that can either be an open or covered window for transmitting radiation to tissue. Costello et al teach the equivalence of stationary and translatable energy applications. It would have been obvious to the artisan of ordinary skill to employ the

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probe translations and optics of Costello et al in the method of Lennox et al ('807) since these are equivalent to the stationary probe and can create a longer lesion or to employ the covered window and flexible sheath of Lennox et al (807) in the method of Costello et al, since this will keep the optic clean, thus producing a method such as claimed.

Claims 5-8, 10-22, 25-33, 40-42, 46-54, 58-72, 100-107, 225, 229-255, 282, 284-297, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al (807) in combination with Costello et al as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Cox et al ('187). Cox et al (187) teach the equivalence of laser, ultrasound, microwave, and cryosurgical energies as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pre-shaped; use of a sheath with a cut out window; and various manipulations of the device including ablating around the pulmonary vein, ablating on the epicardium, and positioning the device in three or more positions. It would have been obvious to the artisan of ordinary skill to employ the maze procedure and ablation means of Cox et al (WO '187) in the combined method of Lennox et al ('807) and Costello et al, or to employ the particular ablation steps of the combined teachings of Lennox et al ('807) and Costello et al in the method of Cox et al (WO '187) since Cox et al (WO '187) teach no particular form for the non cryogenic ablation elements; to employ the various non cryogenic directional ablation element features claimed since these are merely a matter of choice and provides no unexpected result and are known means for providing the desirable functions of Cox et al (WO '187), such as directionality with these equivalent forms of ablation energy discussed by Cox et al (WO '187); to include a cutting member on the distal end of the sheath, since this would allow the cut to be made without introducing an additional tool, thus simplifying the

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procedure, as simplification is desirable, official notice of which is hereby taken; as well as to position the device adjacent to or in contact with the oblique or transverse sinuses as these are both structures associated with pulmonary veins and would be contacted in conjunction with the procedure shown in figure 21 of Cox et al (WO '187); to employ a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this is notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective since this is also notorious in the art; official notice of all of these having already been taken and to perform a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures official notice of which is hereby taken thus producing a method such as claimed.

Claims 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al ('807) in combination with Costello et al as applied to claims 1, 9, 43-45, 96, 97, 298 and 299 above, and further in combination with Swanson et al. Swanson et al teach using temperatures sensors to control ablation and electrodes to pace, map, etc. the heart in a maze procedure wherein the pulmonary vein is encircled. It would have been obvious to the artisan of ordinary skill to employ the sensors and the pulmonary vein encircling device in the combined method of Lennox et al ('807) and Costello et al, since this would enable the performance of beneficial cardiac procedures such as maze or to employ the longitudinally translatable ablation element of the combined method of Lennox et al (807) and Costello et al in the method of Swanson et al,

since this can create longer lesions with a single ablation element, this producing a method such as claimed.

Claims 80-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al ('807) in combination with Costello et al as applied to claims 1, 9, 43-45, 96, 97, 298, and 299 above, and further in view of Kesten et al. Kesten et al teach delivering ablation devices with a pre-shaped sleeve to reach the ventricles via peripheral veins. It would have been obvious to the artisan of ordinary skills to employ the sheath, delivering route, and treatment region of Kesten et al in the combined method Lennox et al ('807) and Costello et al or to employ the directional slidable probe in a sheath of the combined method of Lennox et al ('807) and Costello et al in the method of Kesten et al, since this would allow the treatment of an elongated area without repositioning the device and in either case to treat one of the atria since these chambers are the site of beneficial treatments, official notice of which has already been taken and to employ an alternate access route such as the jugular or subclavian vein, since these are recognized catheter insertion routes in the art, official notice of which has already been taken, thus producing a method such as claimed.

Applicant's arguments filed December 28, 2005 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

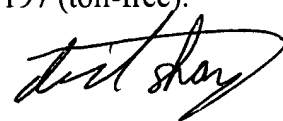
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on Monday through Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330